

February 26, 1992. That application was continuation of application serial No. 07/607,863, filed November 01, 1990. That application was a continuation-in-part of application serial No. 07/486,554, filed February 27, 1990. That application was a continuation-in-part of application serial No. 07/431,664, filed November 03, 1989.

As applicants pointed out in their 37 CFR 1.607 Request for an Interference with a Patent filed on May 14, 1997, the terms of claims 125-144 are supported in the present application. Since the present application is a straight continuation or division of its three immediate parents, the disclosures of those applications is identical to the disclosure of this application. Hence, the claims herein are unquestionably entitled at least to the benefit of the filing date of the 07/607,863 application--i.e., November 01, 1990. That effective filing date removes the Amsden et al. patent as prior art. Moreover, applicants' 37 CFR 1.607 Request pointed out that applicants are also entitled to the benefit of the filing date of their application serial Nos. 431,664 and 486,554 as well.

Since the Amsden et al. reference is not prior art to applicants, the rejection based on that patent should be withdrawn.

II.

Applicants also respectfully request reconsideration and withdrawal of the rejection of claims 125-144 under 35 USC 112 second paragraph. This rejection apparently is based upon the use of functional expressions "an effective amount of" a bile salt enhancer or macromolecular drug. Those limitations are generic, and the precise amounts which are "effective" as penetration enhancers or as "drugs" is dependent upon the particular penetration enhancer or drug that is used. Limitations to functional amounts of ingredients have been approved where the point of novelty does not lie in the discovery yet the particular agents in

question enhance penetration or have therapeutic effects. See, e.g., In re Halleck, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). Compare also the claims in In re Herschler, 200 USPQ 711 (CCPA 1979 ("administration of an amount of said steroidal agent effective to produce the desired physiological effect" and "an amount of DMSO sufficient to effectively enhance penetration of said steroidal agent to achieve the desired physiological effect"); and In re Herschler 474 F.2d 675, 177 USPQ 147 (CCPA 1973) ("an amount of said agent effective to obtain physiological response by said plant" "dimethylsulfoxide in an amount effective to enhance penetration of said agent and to the living tissue of said plant").

Moreover, applicants respectfully point out that claims 125-144 were substantially copied from a U.S. patent for purposes of interference. The claims of the patent are presumed to be definite.

III.

The examiner's attention is respectfully invited to the 37 CFR 1.607 Request for an Interference with a Patent that was submitted upon the filing of this application on May 14, 1997. As applicants pointed out in the Request for Expedited Prosecution that accompanied that Request for Interference, the examination of the application should be conducted with

special dispatch within the Patent and Trademark Office. Accordingly, applicants respectfully request prompt action to initiate the declaration of the interference.

Respectfully submitted,



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